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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,734	01/25/2002	A. Robert Spitzer	0594.00034	9911

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/056,734	Applicant(s) SPITZER, A. ROBERT	
	Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

NOTE: The Examiner, Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/04 has been entered.

Election/Restrictions

NOTE: It has been noted that there was a species election made in this application based on the figures, not the claims. And applicants have elected without traverse (on 6/30/03), figure 5, and claims 22-27 and 30, which read on the elected figure 5.

To clarify the previous restriction requirement, the following restriction requirement of the claims is made.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, 28-29, drawn to a system for treating migraine headache, classified in class 424, subclass 436.
 - II. Claims 22, 25, 27 and 30, drawn to a medicine suppository and method of treating a migraine headache, classified in class 514, subclass 578.
 - III. Claims 31-32, drawn to a method of treatment of migraine, classified in class 424, subclass 436.

The inventions are distinct, each from the other because of the following reasons:

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3. Inventions of group I and group II are related to different apparatus or system and composition. The composition of group II is not disclosed as capable of used in the apparatus of group I inventions. Inventions of group II and group I are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the groups is proper.

4. Inventions of group I and group III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the group III methods can be practiced by a different process and the system of group I can be used in the process of treating some other diseases.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Applicants attorney Andrew Parial on 3/28/05 a provisional election was made without traverse to prosecute the invention of group II, claims 22, 25, 27, 30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-21, 28-29, 31-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Claims 1-21, 28-29, 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/28/05.

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8. Claims 23-24, 26 have been canceled. Claims 22, 25, 27 and 30 are currently being examined in this application.

Priority

9. This application claims priority to provisional applications 60/264,413 filed on 1/26/01 and 60/302,799 filed on 7/3/01.

Status of Previous Rejections

10. In view of the amendments and applicants response filed on 10/22/04, the enablement rejection of claim 30 has been withdrawn.

11. The rejection of claims as being anticipated by US Patent 6,071,927 (Baker et al) has been withdrawn, since the reference composition does not contain valproate as an one of the active ingredient.

12. The rejection of claims 22, 25, 27 have been maintained over US Patent 6,096,742 (Crocker et al) for the reasons discussed below.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 22, 25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,500,221 (Murata et al).

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The instant claims briefly recite a medicine suppository comprising an effective amount of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use.

Murata et al disclose suppository preparation comprising a therapeutically effective amount of an acidic drug or a pharmaceutically acceptable salt thereof which can be absorbed by rectal administration, wherein the acidic drug is sodium valproate (i.e., see claim 1) (reads on the instant claim medicine suppository comprising valproate. Murata et al teach that the suppository preparation contains other additives, such as absorption enhancers, preservatives, stabilizers, surfactants, perfumes, pigments, purified water, and various polymers (i.e., see column 3) (reads on the instant claim 27). The reference clearly anticipates the claimed invention.

15. Claims 22, 25, 27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,268,396 (B1) (Nu et al).

The instant claims briefly recite a medicine suppository comprising an effective amount of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use. Claim 30 recites a method of treating a migraine.

Nau et al teach a method for treatment and prevention of migraine and effective illness by administering a therapeutically effective amount of valproic acid analog 2-n-propyl-4-hexynoic acid (refers to instant claim valproate) (i.e., see abstract). The reference teaches that administration of the compounds of this invention may be by any method used for administering therapeutics, such as rectal administration. The reference teaches pharmaceutical composition for

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the treatment of migraine comprising the 2-n-propyl-4-hexynoic acid or salts thereof, additives, such as preservatives, excipients, fillers, wetting agents, binders, disintegrates, buffers, carriers (i.e., see column 4). The reference teaches that the compositions may be in the form of tablets, capsules, suppositories (refers to the instant claim suppository) (i.e., see column 4). The reference clearly anticipates the claimed inventions.

16. Claims 22, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,369,172 (Schor et al).

The instant claims briefly recite a medicine suppository comprising an effective amount of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use.

Schor et al teach a carrier base material combined with a therapeutically active medicament. The reference teaches that the active ingredient is a type of medication, which can be transmitted into the blood circulation through the rectal tissue (i.e., see column 5), and the medication includes drugs, which treat migraine headaches. The reference teaches the active medicament includes sodium valproate (i.e., see column 6). The reference teaches that for vaginal and rectal suppositories, the release pattern of the active medicament is predetermined (i.e., see column 8). The reference composition comprises carrier, solvents and additives. Thus, the reference clearly anticipates the claimed invention.

17. Claims 22, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,096,742 (Crocker et al).

The instant claims briefly recite a medicine suppository comprising an effective amount

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of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use, and the instant claim suppository recites 'comprising', which is open to other ingredients.

Crocker et al teach pharmaceutical compositions comprising tachykinin receptor agonists in combination with valproate (i.e., see column 12) for treatment of pain, headache, including migraine (i.e., see column 9). The reference teaches that the compounds of the reference and other pharmaceutically active agent may be administered to a patient simultaneously, sequentially, or in combination. The reference further teaches that when using in combination of the present invention, the compound of the present invention and the other pharmacologically active agent may in the same pharmaceutically acceptable carrier (i.e., see column 13). The reference teaches that the pharmaceutical compositions of the inventions as suppositories (i.e., see column 14). The reference teaches that the active ingredient may be compounded with pharmaceutically acceptable carriers, and in addition auxiliary, stabilizing, thickening and coloring agents and perfumes (i.e., see column 14). The reference teaches that the compounds of the inventions may be administered rectally (i.e., see column 15).

The reference clearly anticipates the claimed invention.

Response to Arguments

18. Applicant's arguments with respect to claims 22, 25, 27, 30 have been considered but are moot in view of the new ground(s) of rejection.

19. Applicant's arguments filed on 10/22/04, regarding the rejection of claims over US Patent 6,096,742 (Crocker et al) have been fully considered but they are not persuasive. Applicants

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argue that the reference discloses compositions including additional components, and since the instant claimed invention does not include those additional components.

Applicants arguments regarding the composition comprising additional components have been considered, and are not persuasive. Because the instant claim recites 'a medicine suppository comprising', which is open to valproate and other ingredients. Thus the rejections over Crocker et al has been maintained.

Conclusion

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

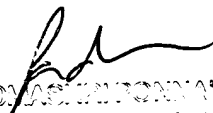
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

04 April 2005



PADMASHRI PONNALURI
PRIMARY EXAMINER